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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,588	01/21/2004	Grigoriy S. Tchaga	CLON-056US2	3721

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BOZICEVIC, FIELD & FRANCIS (BD BIOSCIENCES)
1900 UNIVERSITY AVENUE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER

ROOKE, AGNES BEATA

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/762,588

Applicant(s)

TCHAGA ET AL.

Examiner

Agnes B Rooke

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>May 13, 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-17 are pending.

Applicant's election with traverse of Group II, Claims 11-17 in the reply filed on December 3, 2004 is acknowledged. The Applicant did not state any grounds for his traversal. The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 1-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected claims. Claims 11-17 are under examination. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP paragraph 821.01.

This application claims benefit of 60/441,084, filed on January 21, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 11, its it is not clear whether the two metal ion chelate resins are in separate containers in a kit, or whether these two resins are next to each other in one composition in a kit, or whether those two resins are mixed together in one composition in a kit. Also, the Applicant refers to a *first* metal ion *chelate* resin and *second* metal ion

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affinity resin. Therefore, it is not clear if "chelate" and "affinity" columns mean the same thing. Further, how can the chelate resin be *first* without a *second*, or affinity resin be *second* without a *first*?

In Claims 12-15, if the resins are the same, what difference does it make, which has the hard or intermediate ion?

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-17 are rejected under judicially created doctrine of obviousness-type double patenting.

Claims 11-17 are rejected as being unpatentable over Claims 1-12 and 20-23 of the U.S. 6,703,498. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claims are not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 11-17 are generic to all that is recited in Claims 1-12 and 20-23 of the U.S. 6,703,498. That is, Claims 1-12, and 20-23 of the U.S. 6,703,498 fall entirely within the scope of Claims 11-17, or in other words, Claims 11-17 are anticipated by Claims 1-12 and 20-23 of the U.S. 6,703,498.

The instant Claims 11-17 refer to the metal ion chelate resins with hard and intermediate metal ions bound to it peptide, which are used for purification of proteins. Claims 1-12 and 20-23 of the U.S. 6,703,498 refer to polymeric ion metal ion affinity compounds bound to metal chelating ligands, which are used for separating analytes. See Columns 17-19.

Therefore, obviousness type double patenting rejection is made against Claims 11-17 over Claims 1-12 and 20-23 of the U.S. 6,703,498, because both of the inventions claim the same composition, such as metal chelate resin with intermediate or hard metal ions, and both of the inventions can be used for separation of proteins.

Clearly, the practice of invention of the U.S. 6,703,498 would infringe on claims of the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Porath et al., "Immobilized Metal Ion Affinity Adsorption and Immobilized Metal Ion Affinity Chromatography of Biomaterials. Serum Protein Affinities for Gel-Immobilized Iron and Nickel Ions," *Biochemistry* (1983), 22, p. 1621-1630.

Porath et al. teach metal chelate affinity chromatography for purification of serum proteins, where gels are loaded with the same or different metal ion, for example Ni(II) and Fe(III) (Claims 11-15, and 17). See *Abstract*.

Porath et al. prepared different columns, for example "IDA-Sepharose 6B" or "TED-Sepharose 4 B" with bound Ni(II) or bound Fe(III), where each chelator gel was packed in a separate column (Claims 11-15, and 17). See page 1622 (*Materials and Methods*

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section). Different combinations of columns were formed, where two or more columns were packed with one type of chelator gel (e.g., TED-Sepharose) and loaded with different metal ions (e.g., Ni(II) or Fe(III)) to form "tandem columns" (Claims 11-15, and 17). See page 1622 (*Chromatography* section). Different combinations of "tandem columns" were created where Fe(III)-TED bed proceeded Ni(II)-TED or Ni(II)-TED bed preceded Fe(III)-TED bed (Claims 11-15, and 17) See page 1624 (*Results* section). The following buffers were used for extraction, wash, and elution purposes: 0.05M sodium acetate and 0.1 M NaCl, pH 5.5; 0.1 M Tris-HCl, pH 8.1; 0.5 M sodium acetate, pH 5.5; and 1M glycine, pH 9.0 (Claims 11 and 16).

Therefore, Claims 11-17 of the instant invention are anticipated by Porath et al. since all limitations of the claims are addressed.

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the

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Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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A handwritten signature in black ink, reading "Karen Cochrane Carlson PhD". The signature is fluid and cursive, with the "P" in "PhD" being particularly large and stylized.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER